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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,836	03/29/2001	Triptikumar Mukhopadhyay	085933/0117	5592

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EXAMINER

MOHAMED, ABDEL A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 11/19/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,836

Applicant(s)

MUKHOPADHYAY ET AL.

Examiner

Abdel A. Mohamed

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

ACKNOWLEDGMENT FOR PRIORITY, PRELIMINARY AMENDMENT, IDS, STATUS OF THE APPLICATION AND CLAIMS

1. This application is filed under 35 U.S.C. 371 on 3/29/01 having a filing date of 4/22/99 of PCT/EP99/02715. Acknowledgment is made of Applicant's claim for priority based on European Patent Office (EPO) application number 98107397.6 having a filing date of 4/23/98. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119, which papers have been placed of record in the file. The Information Disclosure Statement (IDS) and Form PTO-1449 and the preliminary amendment filed 3/29/01 are acknowledged, entered and considered. In view of Applicant's request claims 3 and 4 have been amended. Thus, claims 1-4 are now pending.

OBJECTION TO THE SPECIFICATION

2. The specification is objected because there are no Headings disclosed in the disclosure and there are no description for the drawings (Figures). Note that the specification should also be amended to be commensurate with the objection of the Draftsman (See Form PTO-948, Paper No. 9). Further, the following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the Applicant's use.

ARRANGEMENT OF THE SPECIFICATION

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should

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appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (I) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

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OBJECTIONS TO TRADEMARKS AND THEIR USE

3. The use of trademark "Sephadex LH-20®" has been noted in this application. The trademark has not been capitalized, it should be capitalized whenever it appears and be accompanied by the generic terminology. Although, the use of trademark is permissible in patent applications, the proprietary nature of the mark should be respected and every effort made to prevent its use in a manner which might adversely affect their validity as trademark.

Further, the specification which specifies the generic terminology should include published product information sufficient to show that the generic terminology or the generic description is inherent in the article referred by the trademark. This description requirement is made because the nature and composition of articles denoted by trademark can change and affect the adequacy of the disclosure.

CLAIM REJECTION-35 U.S.C. § 112, FIRST PARAGRAPH

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Conversion step(s) is/are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Independent claim 1 and dependent claim 2 recite

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a process for the conversion of echinocandin class of peptides to their C4-homotyrosine monodeoxy analogues of the formula I....., however, the claims do not recite the essential process step(s) for achieving the result of conversion of echinocandin class of peptides. Thus, the critical step(s) necessary for achieving the invention should be included at least in independent claim 1.

CLAIMS REJECTION-35 U.S.C. § 112^{2nd} PARAGRAPH

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 1 is indefinite and incomplete in failing to recite method step(s) of a process for the conversion of echinocandin class of peptide of the formula I. Although, claim 1 states "conversion, reduction, protection, deprotection, purification.....", but, the claim does not use active method step(s) i.e., converting, reducing, protecting, deprotecting, purifying.....ect., and it is not clear how the step(s) of conversion of echinocandin class of peptides to their C4-homotyrosine monodeoxy analogues of formula I by selective reduction under neutral condition

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without prior protection/deprotection of C5-ornithine hydroxyl group and purification of the monodeoxy compound thereof is achieved without active method step(s). There is/are no active method step(s) for reduction, protection/deprotection and purification. Thus, use of active method step(s) would obviate this rejection.

Claim 1 is indefinite in the recitation "without prior protection/deprotection" because it contains the use of an alternative expression wherein the limitation covers two elements, i.e., "protection" is not the same as "deprotection" and vice versa.

Claim 1 recites the limitation "from the crude reaction mixture", in last lines 1 and 2. There is insufficient antecedent basis for this limitation in claim 1.

Claim 2 is indefinite and confusing in the recitation "wherein Mulundocandin is converted to Deoxymulundocandin" because it is not clear how such conversion occurs since there is no any method step(s) of conversion of Mulundocandin to Deoxymulundocandin either in claim 1 or in claim 2. Appropriate clarification is required.

Claim 3 recites the limitation "wherein the reduction reaction" in line 1. There is insufficient antecedent basis for this limitation in claim 1 or claim 3.

CITATION OF RELEVANT PRIOR ART

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Rodriguez (U.S. Patent No. 5,677,423) teaches a process for removing β -hydroxy groups from β -hydroxy containing compounds which encompass complexes of cyclic peptides such as compounds of the echinocandin family.

Balkovec et al. (U.S. patent No. 5,159,059) disclose a process for producing a compound such as echinocandin and echinocandin-like cyclohexapeptide by selectively reducing said compound in a strong acid medium.

Mukhopadhyay et al. (The Journal of Antibiotics, Vol. 40, No. 3, pp. 281-289, March 1987) report the preparation of mulundocandin which is a new lipopeptide antifungal antibiotic by acid hydrolysis.

Mukhopadhyay et al. (The Journal of Antibiotics, Vol. 45, No. 5, pp. 618-623, May 1992) teach the preparation of a new echinocandin type antifungal antibiotic, deoxymulundocandin by acid hydrolysis.

The instantly claimed invention as claimed in Claims 1-4 appears to be free of the cited prior art of record because none of the cited prior art either singularly or in combination teach or suggest a process for the conversion of echinocandin class of peptides of the formula I (Cyclic hexapeptides having a lipophilic side chains) via single step selective reduction of the C4-homotyrosine (C4-htyr) hydroxyl group of echinocandins to their monodeoxy analogues under neutral condition (pH 7) without prior protection/deprotection of the equally facile C5-Orn (ornithine) hydroxyl group and purification of the monodeoxy compound from the crude reaction

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mixture, wherein mulundocandin is converted to deoxymulundocandin and the reduction reaction is carried out by hydrogenolysis with the ratio of 6.8 ml of Raney nickel per millimole of mulundocandin in ethanol at pH 7 and room temperature.

CONCLUSION AND FUTURE CORRESPONDENCE

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m.. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

AM Mohamed/AAM

November 18, 2002

Abdel A. Mohamed
ABDEL MOHAMED
PATENT EXAMINER
GROUP 1800
TC 1600